K083528

JAN 28 2009

510k Summary of Safety and Effectiveness

Submitted By: Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116

Date: November 26, 2008

Contact Person: Kim P. Kelly, Director, Regulatory Affairs
Tel: (901) 399-6566 Fax: (901) 399-1557

Proprietary Name: Smith & Nephew Adaptor Cable

Common Name: Accessory, Electrosurgical cutting and coagulation device

Classification Name and Reference:
21 CFR 878.4400,Electrosurgical cutting and coagulation device and accessories - Class II

Device Product Code and Panel Code: GEI

Device Description:
The Smith & Nephew Adaptor Cable has been designed as an accessory device to the Smith & Nephew Electrothermal Spine System and will provide the option of bipolar energy distribution. The subject device is designed to be used with Smith & Nephew Electrothermal generators, Radiofrequency (RF) denervation probes, and cannulae to create RF heat lesions for the treatment of pain. This configuration eliminates the need of a grounding pad, allowing for return of the delivered energy via a secondary non-active RF probe.

Intended Use:
The Smith & Nephew Adaptor Cable is intended for connecting a Smith & Nephew Radiofrequency Denervation Probe to Smith & Nephew RF Lesion Generators.

Technological Characteristics:
The Smith & Nephew Adaptor Cable is similar to legally marketed devices in that they share similar indications for use and incorporate similar technological characteristics.

Substantial Equivalence Information:
When compared to the predicate device listed below, substantial equivalence is based on similarities in design features and overall indications for use:

- Neurotherm NT 1000 RF Lesioning System – K052878
- Stryker RF Parallel Bipolar Adapter Cable – K061660

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2009

Smith & Nephew, Inc.
% Ms. Kim P. Kelly
Director, Regulatory Affairs
1980 Nonconnah Boulevard
Memphis, Tennessee 38132

Re: K083528
Trade/Device Name: Smith & Nephew Adaptor Cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 26, 2008
Received: November 28, 2008

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K083528

Device Name: Smith & Nephew Adaptor Cable

Indications for Use:

The Smith & Nephew Adaptor Cable is intended for connecting a Smith & Nephew Radiofrequency Denervation Probe to Smith & Nephew RF Lesion Generators.

Prescription Use: X OR Over-The-Counter

(Per 21 CFT 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083528